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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/016,282	12/06/2001	Thomas W. Konowalchuk	LFCTP001X3	4202

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EXAMINER	
HUI, SAN MING R	
ART UNIT	PAPER NUMBER
1628	

NOTIFICATION DATE	DELIVERY MODE
11/27/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

USPTO@wavsip.com

Office Action Summary	Application No.	Applicant(s)	
	10/016,282	KONOWALCHUK ET AL.	
	Examiner	Art Unit	
	San-ming Hui	1628	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 August 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-9,12-18 and 20-26* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-9,12-18 and 20-26* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *1/13/09*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicant's amendments filed August 21, 2009 have been entered.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-6, 9, 12-14, 16-18, 20-23, and 25-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yu et al. (US Patent 5,385,938) in view of Poli et al. (Food Chemistry, 1979; 4(3): 251-258), Wenninger (International Cosmetic Ingredient Dictionary and Handbook, 7th ed., Vol. 1, page 163-168), and Merck Index (11th ed., 1989, Glycolic acid monograph 4394, page 4399).

Yu et al. teaches a topical composition with glycolic acid is the active and about 12.4% ethanol as solvent (See col. 14, Example 1). Yu et al. also teaches that the composition has pH of 3.0 (See col. 14, Example 1). Yu et al. also teaches that the glycolic acid composition is useful to eradicate lesions such as warts, which is a viral infection of papallomas virus (See col. 30, line 10 – col. 31, line 2). Yu et al. also teaches that other pharmaceutically acceptable vehicles other than water and ethanol may be used (See col. 13, lines 11-13). Yu et al. also teaches that the concentration of hydroxyacids, including glycolic acid, may range from 0.02 to 12M (See col. 13, lines 17-19). Yu et al. also disclosed that the amphoteric compounds are not necessarily present in the composition of Yu et al. in order to have antiviral activities (See col. 11,

lines 55-59). Yu et al. also teaches that the composition may be formulated into gel, ointment, cream, lotion, and other cosmetic and pharmaceutical preparation (See col. 13, lines 4-6).

Yu et al. does not expressly teach 1,3-butanediol, as known as butylenes glycol, is useful as pharmaceutical vehicle. Yu et al. does not expressly teach that the glycolic acid containing topical composition as useful in the prophylaxis of lesions caused by viruses within the Herpesvirdae. Yu et al. does not expressly teach the composition having a specific pH of 2.45. Yu et al. does not expressly teach the concentration of glycolic acid in the composition as 0.6%.

Poli et al. teaches that glycolic acid is virucidal against herpevirus (See particularly page 253, Table 1).

Wenninger teaches that butylenes glycol as useful as solvent in numerous cosmetic marketed products (See page 163-168).

Merck Index teaches that the pH 0.5% of glycolic acid solution as 2.50 (See the glycolic acid monograph). Examiner notes that 0.5% of glycolic acid is about 0.31M.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to employ butylenes glycol as solvent in the topical wart-treating composition of Yu et al. and adjust the pH to 2.45. It would have been obvious to one of ordinary skill in the art at the time the invention was made to employ the glycolic acid containing topical composition, in the prophylaxis of lesions caused by viruses within the Herpesvirdae. It would have been obvious to one of ordinary skill in the art at the time

the invention was made to incorporate 0.6% of glycolic acid to the herein claimed prophylactic method.

One of ordinary skill in the art would have been motivated to employ butylenes glycol as solvent in the topical wart-treating composition of Yu et al. and adjust the pH to 2.45 because butylenes glycol is known to be useful in cosmetic products as solvent. Employing any known solvents, including butylene glycol, into a topical composition would have been reasonably expected to be useful in formulating a topical wart-treating composition and treating the same. Moreover, the optimization of result effect parameters (e.g., pH of the composition and the amount of active (glycolic acid)) is obvious as being within the skill of the artisan since 0.31M is within the range disclosed in Yu et al., absent evidence to the contrary.

One of ordinary skill in the art would have been motivated to employ the glycolic acid containing topical composition in the prophylaxis of lesions caused by viruses within the Herpesvirdae. Based on the teachings of Poli et al. and Yu et al., glycolic acid is known to be effective in killing herpes virus. Therefore, applying a glycolic acid composition to reduce the number of herpes viruses, and thereby reducing the chances for herpes viruses to cause the lesions, would have been reasonably expected to be effective.

Claims 1, 7-8, 15, and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bhatia et al. (Indian Journal of Animal Sciences 1998; 68(6): 518-520, reference of record) in view of Disinfectant Drugs (Therapeutic Products

Programme Guidelines published by Health Canada, April 1999, pages 42-45) and Remington (Remington's Pharmaceutical Sciences, 18th ed., 1990, pages 218-219 and1314-1315).

Bhatia et al. teaches that 0.4N hydrochloric acid is effective in inactivating sheep pox virus (See particularly page 519, col. 1, Table 1 and col. 2, third paragraph). Bhatia et al. also teaches that the "Ranch" strain of goat pox virus is more sensitive in acidic pH 3.0 as there was 5 log fall in the titer in the acidic pH (See page 519, col. 2, third paragraph).

Bhatia et al. does not expressly teach the use of hydrochloric acid with an alcohol, in the amount of 0.2% to 30% or 0.2% to 12.5% in volume, in the method of prophylaxis of lesions caused by Poxviridae such as molluscum contagiosum. Bhatia et al. does not expressly teach the pH of the composition as 2.45.

Disinfectant Drugs teaches isopropanol 15% or above is effective as a single medicinal ingredient for disinfecting contact lens (See page 43, Table).

Remington teaches that isopropanol is a very good pharmaceutical solvent, which is comparable to ethanol (see page 219, col. 1). Remington also teaches that ethanol is a very good pharmaceutical solvents (See page 1314, col. 2 – page 1315, col. 1).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate isopropanol, in the amount of 0.2% to 30% or 0.2% to 12.5% in volume, with hydrochloric acid in a method for the prophylaxis of lesions caused by Poxviridae such as molluscum contagiosum. It would have been obvious to

one of ordinary skill in the art at the time the invention was made to adjust the pH of the composition to 2.45.

One of ordinary skill in the art would have been motivated to incorporate isopropanol, in the amount of 0.2% to 30% or 0.2% to 12.5% in volume, with hydrochloric acid in a method for the prophylaxis of lesions caused by Poxviridae such as molluscum contagiosum because isopropanol is known to be useful as both a solvent and a disinfectant and hydrochloric acid is known to have virucidal activities against pox viruses. Employing hydrochloric acid in a method of prophylaxis of lesions caused by pox viruses, such as molluscum contagiosum, would have been reasonably expected to be effective. Incorporating a well-known commonly used pharmaceutical solvent, such as isopropanol, into a topical formulation and optimizing the amount of such solvent used for the same purpose would be obvious as being within the purview of skilled artisan. Moreover, adding a secondary disinfectant such as isopropanol to control the secondary infection which may be accompanied by the outbreaks or lesions caused by such virus infection would also be reasonably expected to be useful. Furthermore, optimization of the pH to 2.45 would be considered obvious as being within the purview of skilled artisan.

It is applicant's burden to demonstrate unexpected results over the prior art. See MPEP 716.02, also 716.02 (a) - (g). Furthermore, the unexpected results should be demonstrated with evidence that the differences in results are in fact unexpected and unobvious and of both statistical and practical significance. *Ex parte Gelles*, 22 USPQ2d 1318, 1319 (Bd. Pat. App. & Inter. 1992). Moreover, evidence as to any unexpected

benefits must be "clear and convincing" *In re Lohr*, 137 USPQ 548 (CCPA 1963), and be of a scope reasonably commensurate with the scope of the subject matter claimed, *In re Linder*, 173 USPQ 356 (CCPA 1972). In the instant case, the data in page 9, 10, 14-16 has been considered, but are not found persuasive. The data merely demonstrates the upper limit of effective pH for virucidal activities. Please note that the pH of the composition mainly depend on the amount of acids present in the composition. Therefore, the data regarding the pH limitation is considered as a reflection of what the effective amount of glycolic acid required in order for the composition to be virucidal (See page 10 of the instant specification, Tables 2 and 3). This is seen to be an expected effect based on the cited prior art. No convincing and clear unexpected result is seen.

Response to Arguments

Applicant's arguments filed August 21, 2009 averring the cited prior art's teaching away have been fully considered but they are not persuasive. The applicant argues that Yu et al. teaches the use of the amphoteric compound as necessary for Yu's invention and since the instant claims excludes such compound, the Yu reference alone or combination do not motivate one of ordinary skill in the art to arrive at the instant invention. The examiner respectfully disagree the conclusion applicant derived, especially in view of the teachings of the cited prior art **as a whole**. The examiner notes based on the teachings of Poli et al. and Yu et al., glycolic acid alone, i.e., without the amphoteric aompound, is known to be effective in killing herpes virus. Therefore,

applying a glycolic acid composition to reduce the number of herpes viruses, and thereby reducing the chances for herpes viruses to cause the lesions, would have been reasonably expected to be effective. The pH of the glycolic acid solution can be adjusted to the herein claimed pH. As discussed in the rejection above, the optimization of result effect parameters (e.g., pH of the composition and the amount of active (glycolic acid)) is obvious as being within the skill of the artisan since 0.31M is within the range disclosed in Yu et al., absent evidence to the contrary. It has been held that it is within the skill in the art to select optimal parameters, such as amounts of ingredients – in this case glycolic acid, in a composition in order to achieve a beneficial effect. See *In re Boesch*, 205 USPQ 215 (CCPA 1980). It is also noted that "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).

Applicant's arguments with regard to the Cancadian patent Pamukoff is considered moot since Pamukoff is not cited in the rejection under 35 USC 103(a).

Applicant's arguments with regard to the irritability of glycolic acid or hydrochloric acid have been considered, but are not found persuasive. The examiner notes that the instant claims do not recite the location of the composition to be applied onto. Furthermore, the instant method is directed to the prevention of lesions, which implies that no lesions are formed. Therefore, it is unlikely the instant composition will be applied to the mucous membrane, as applicant asserts. Therefore, possessing the

teachings of the cited prior art, one of ordinary skill in the art would have been motivated to employ the herein claimed ingredients in the instant method.

Applicant's arguments with regard to the limited additional agents to be combined with hydrochloric acid have been considered, but are not found persuasive. It is clear that the short list of agents as safe to combine with isopropanol as disinfectant. However, the cited prior art does not limit other agents to be combined with isopropanol nor discourage other agents to be combined with isopropanol. There is no indication that the combination is limited to those agents disclosed in the prior art. One of ordinary skill in the art, possessing the teachings of the cited prior art as a whole would not view such list of combination as exhaustive and limiting. Rather, adding a secondary disinfectant such as isopropanol to hydrochloric acid to control the secondary infection which may be accompanied by the outbreaks or lesions caused by such virus infection would also be reasonably expected to be useful.

No claims are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to San-ming Hui whose telephone number is (571) 272-0626. The examiner can normally be reached on Mon - Fri from 9:00 to 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brandon Fetterolf can be reached on (571) 272-2919. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

San-ming Hui
Primary Examiner
Art Unit 1628

/San-ming Hui/

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